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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/240,410 01/29/99 MICHALOVICH

D GP-30039

HM12/0201

EXAMINER

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GRASER, J

ART UNIT

PAPER NUMBER

1641

12

DATE MAILED:

02/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/240,410

Applicant(s)

Michalovich et al.

Examiner

Graser, Jennifer

Group Art Unit

1641



☒ Responsive to communication(s) filed on Amendment A, 11/15/99.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 2, 6-8, 10, 11, and 13-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 6-8, 10, 11, 16, and 19 is/are allowed.

☒ Claim(s) 2, 17, and 20 is/are rejected.

☒ Claim(s) 13-15 and 18 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted 11/15/99, Paper No.11/A is made. Claims 2, 6-8, 10, 11 and 13-20 are currently pending.

#### ***Information Disclosure Statement***

2. As stated in the previous Office Action, the information disclosure statement filed 4/19/99 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there are no publication dates on the PTO-1449 form. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

#### ***Rejections which have been overcome:***

3. All 112, second paragraph rejections have been overcome by the amendments to the claims. Additionally, the 102(b) prior art rejections have been overcome by the Amendments and Applicants' arguments. Further, it was confirmed that Genbank Accession No. AF030698 was not publicly available prior to Applicants' priority date of 1/30/98.

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***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 17 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for polynucleotides which comprise a polynucleotide sequence that has "at least 95% identity to a nucleotide sequence which encodes a polypeptide comprising the amino acid of SEQ ID NO:2, wherein said polynucleotide sequence may include up to  $n_n$  nucleotide alterations..." (as recited in claim 2). This claim language allows for 93 nucleotide alterations to the degenerate sequences. However, the specification provides no guidance as to what nucleotides may be changed without causing a detrimental effect to the protein to be produced. It is unpredictable as to which nucleotides can be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where the amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spacial orientation of

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binding and catalytic sites. These regions can tolerate only very little or no substitutions. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the invention without undue experimentation.

The specification is also not enabled for an isolated polynucleotide comprising a polynucleotide sequence that has "at least 95% identity to that of SEQ ID NO:1, wherein said polynucleotide sequence may include up to  $n_n$  nucleotide alterations over the entire length of SEQ ID NO: 1...." (as recited in claim 17). This claim language allows for numerous alterations to the nucleotide sequence. However, the specification provides no guidance as to what nucleotides may be changed without causing a detrimental effect to the protein to be produced. It is unpredictable as to which nucleotides can be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where the amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spatial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the invention without undue experimentation.

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The specification is also not enabled for “an isolated polynucleotide which is obtained by screening a library under stringent conditions with a probe comprising a nucleotide sequence which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2 ... wherein said polynucleotide obtained comprises at least 50 nucleotide bases” (claim 20). There is no functionality recited for the “isolated polynucleotide which is obtained by...” and the claim does not require that the “at least 50 nucleotides be contiguous”; therefore, it is unclear what function this nucleotide sequence could serve. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the invention without undue experimentation.

***Allowable Subject Matter***

6. Claims 6, 7, 8, 10, 11, 16 and 19 are allowed. Claims 13, 14, 15 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM. Please note that the name of the Examiner of record has changed from Jennifer Shaver to Jennifer Graser.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jennifer Graser*  
**JENNIFER GRASER**  
**PATENT EXAMINER** 1/28/10